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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,270	08/05/2005	Christian Krebs	18661-002US2US1/INO10504P	2861
26161	7590	08/21/2008		
FISH & RICHARDSON PC			EXAMINER	
P.O. BOX 1022			NASSER, ROBERT L	
MINNEAPOLIS, MN 55440-1022				
			ART UNIT	PAPER NUMBER
			3735	
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			08/21/2008 PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,270

Applicant(s)

KREBS ET AL.

Examiner

ROBERT L. NASSER

Art Unit

3735

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 and 20-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 43-46 and 65-68 is/are allowed.
- 6) ☒ Claim(s) 14-18, 22, 25-28, 31-37, 39, 41, 42, 57-64 is/are rejected.
- 7) ☐ Claim(s) 20, 23, 24, 29, 30, 38 and 40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/2008* has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14-18, 22, 25-28, 31, 35, 36, 37, 39, 41, 42, and 57-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein et al 2004/0258772 in view of Shaffer et al 5429123. Claim 14 is rejected in that in paragraph [0069] Otterbein discloses the following: an apparatus including a CO source – i.e. a standard tank of gas mixed with carbon monoxide and a dosing unit – Otterbein says the gas can be delivered bedside where it is mixed in a blender. Hence the blender is the dosing unit. In addition, Otterbein in paragraph [0069] discloses a ventilator to deliver the CO to the patient. It also has a sensor means to measure CO in the blood (see discussion of measuring COHB and exhaled CO through side port of the ventilator). Finally, Otterbein has a controller to control the delivery of CO based on the measured values.

While the reference does not explicitly describe a controller, it says that the CO exposure can be adjusted based on the patient's health status and on the basis of the markers. Otterbein further describes the above mechanism as a fail safe mechanism. Shaffer teaches a similar system that monitors gas concentrations and adjusts the supply to a mixer based on monitored concentrations, where the system is controlled by a microprocessor. It would have been obvious to modify Otterbein to use such a processor, to eliminate human error from the process. Claim 15 is rejected in that the carbon monoxide is a source of CO in a mixture and the blender mixes the mixture into the breathing gas of a patient. Claim 16 is rejected in that the delivering unit is a ventilator. Claim 17 is rejected in that Otterbein states that the CO levels are monitored by measuring the COHb levels AND the CO in exhaled breath. Claim 18 is rejected in that it would have been obvious to activate an alarm when the CO concentration exceeded a limit, to alert medical personnel of potential hazardous conditions. Claims 22 and 25 are rejected in that Otterbein discloses measuring CO by measuring carboxyhemoglobin and CO amount in the expired air. Claim 26 is rejected in that Otterbein shows a method which uses the device of claim 14 that includes administering exogenous CO to a patient, measuring the blood CO concentration, comparing the CO concentration to a harmful limit, i.e. a preset desired safety limit, and adjusting the CO levels supplied to the patient if the limits are exceeded. Claim 27 is rejected in that the method is repeated. Claims 28 and 31 are rejected in that Otterbein discloses measuring CO by measuring carboxyhemoglobin and CO amount in the expired air. Claims 35-37 and 42 are rejected for the reasons given above. Claim 39 is rejected in

that one of the ways to vary the CO concentration is to add more oxygen to the mixture. Claim 41 is rejected in that since the patient is on a ventilator, the patient is artificially breathing. Claims 57-64 are rejected in that the exact threshold level would have been obvious to one skilled in the art.

Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein in view of in view Shaffer et al, as applied to claims 14-18, 22, 25-28, 31, 35, 36, 37, 39, 41, 42, and 57-64, further Aldrich 5810723. Aldrich teaches measuring carboxyhemoglobin noninvasively with oximetry. Hence, it would have been obvious to modify Otterbein to use such a measurement technique, as it is merely the substitution of one known technique for another.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Otterbein in view Shaffer et al, as applied to claims 14-18, 22, 25-28, 31, 35, 36, 37, 39, 41, 42, and 57-64 further in view of Stone 5293875. Aldrich teaches measuring carboxyhemoglobin spectroscopically. Hence, it would have been obvious to modify Otterbein to use such a measurement technique, as it is merely the substitution of one known technique for another.

Claims 20, 23, 24, 29, 30, 38 and 40 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 43-56 and 65-68 are allowable.

Claim 20 defines over the art of record in that none of the art has the claimed filter.

Claims 23 and 29 define over the art in that none of the art monitors Co concentration from levels of oxyhemoglobin.

Claims 24 and 30 define over the art of record in that none of the art monitors CO levels by monitoring enzyme activity in the blood.

Claims 38, 43-56, and 65-68 define over the art in that none of the art delivers CO to the patient in pulses that are triggered by inhalation or exhalation.

Claim 40 defines over the art in that none of the art delivers Co to the patient in pulses based on the CO concentration.

Applicant's arguments filed 7/21/2008 have been fully considered but they are not moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner
Art Unit 3735

RLN
March 17, 2008